This Program Announcement expires on July 1, 2004, unless reissued.

BIOLOGY OF THE MENOPAUSAL PROCESS AND ASSOCIATED HEALTH CONDITIONS DURING AND AFTER MENOPAUSE

Release Date: March 14, 2001

PA NUMBER: PA-01-067

National Institute on Aging
National Institute of Arthritis and Musculoskeletal and Skin Diseases
National Institute of Child Health and Human Development
National Institute of Diabetes and Digestive and Kidney Diseases

THIS PA USES THE "MODULAR GRANT" AND "JUST-IN-TIME" CONCEPTS. IT INCLUDES DETAILED MODIFICATIONS TO THE STANDARD APPLICATION INSTRUCTIONS THAT MUST BE USED WHEN PREPARING APPLICATIONS IN RESPONSE TO THIS PA.

This Program Announcement replaces Program Announcement, PA-95-006 (Biology of the Menopause: Change of Ovarian Function), which was published in the NIH Guide November 18, 1994.

PURPOSE

The National Institute on Aging (NIA), in collaboration with the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Child Health and Human Development (NICHD), and the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK), invite applications to support research that elucidates molecular and cellular mechanisms underlying the menopausal process, and the pathophysiologic connections of that process with various health problems and conditions of peri- and postmenopausal women. This program announcement addresses a) the underlying biology of age- and menopause-related changes in the hypothalamic-pituitary-ovarian (H-P-O) axis that result in the dramatic hormonal changes experienced across the menopausal transition, and b) how the biology of menopause impacts the menopause-related increase in health problems and conditions associated with the brain, cardiovascular, skeletal, genitourinary and other physiologic systems.

HEALTHY PEOPLE 2010

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS led national activity for setting priority areas. This Program Announcement (PA), Biology of the Menopause and Associated Health Conditions, is related to one or more of the priority areas. Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople/.

ELIGIBILITY REQUIREMENTS

Applications may be submitted by domestic and foreign for-profit and non-profit organizations, public and private, such as universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the Federal government. Racial/ethnic minority individuals, women, and persons with disabilities are encouraged to apply as principal investigators.

MECHANISM OF SUPPORT

The mechanism of support will be the National Institutes of Health (NIH) individual research project grant (R01). Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicant.

Specific application instructions have been modified to reflect "MODULAR GRANT" and "JUST-IN-TIME" streamlining efforts being examined by NIH. Complete and detailed instructions and information on Modular Grant applications can be found at: http://grants.nih.gov/grants/funding/modular/modular.htm.

RESEARCH OBJECTIVES

Background

The ovary of the premenopausal non-pregnant human female, as well as the ovary of various animal species, serves as the body's primary source of estradiol-17 beta (E2), the steroid hormone associated with protection of the premenopausal woman from a variety of potential postmenopausal health problems, such as increased risk for decline in cardiovascular, skeletal, and genitourinary system function, and for increased incidence of hot flashes. In addition to E2, the premenopausal ovary also secretes other steroid hormones, such as progestins and androgens, and the glycoprotein, inhibin. Progestins, androgens and inhibin all have

incompletely understood functions within the hypothalamic-pituitary-ovarian (H-P-O) axis and much less well-defined roles in the proper functioning of peripheral tissues.

The change in ovarian function across the menopause is accompanied by the loss of virtually all of the primordial and developing follicles residing within the ovary. From a non-replenishable store of several million primordial follicles formed within the developing human ovary during gestation, approximately 25,000 follicles remain at the start of the final 12-15 years of menstrual cycling. These remaining follicles appear to undergo an accelerated rate of loss of over twice that of the first two decades of reproductive life. The molecular and cellular mechanisms responsible for this acceleration of follicular loss are virtually unknown. Consequently only several hundred or less apparently gonadotropin-insensitive follicles remain in the ovary at the time of menopause, a number likely to be too small to sustain the H-P-O interactions required for regular menstrual cyclicity.

Follicular atresia is the predominant fate of ovarian follicles. Of the millions of follicles initially present in the ovary, well over 99 percent are depleted over the woman's reproductive life span through atresia. Except for the single ovulatory follicle per month in a normally cycling woman, all of the growing pool of antral follicles is resorbed within the ovary by atresia. Even women not cycling due to oral contraceptive usage or pregnancy lose ovarian follicles at rates comparable to those in cycling women. The underlying mechanism of atresia of antral follicles in diverse species, including humans, appears to involve apoptosis in various follicular cells. The molecular and cellular mechanisms through which these apoptotic processes are regulated are just starting to be explored.

Menstrual cycles in regularly cycling middle-aged women gradually grow shorter due to a shorter follicular phase, while the length of the luteal phase generally remains constant. As women enter the perimenopausal period, their cycles gradually lengthen, as the fraction of ovulatory cycles declines and cycles become irregular. Early follicular phase FSH levels begin to rise about five years preceding the menopause, even in regularly cycling women. Inhibin B, a potential biomarker of ovarian follicular function in the pre- and perimenopausal woman, is reported to decline in older ovulatory women with increased serum FSH levels. Characteristics of pulsatile pituitary gonadotropin secretion driven by changes in hypothalamic GnRH secretion in women in their 40s with normal cycles and hormonal levels may explain the rise in FSH levels. Thus, age-related changes in the H-P-O axis may to play an important role in the menopausal process.

LH levels become elevated roughly one year prior to menopause. Data on serum levels of E2 and progesterone suggest elevated levels of E2 and diminished levels of progesterone relative to

young premenopausal women during at least part of the peri-menopause. Changes in the formation and function of the corpus luteum during the perimenopause are not well described.

Thus, menopause marks a dramatic change in ovarian function. Prior to menopause, the ovary participates as a key component of the dynamic hormonal orchestration of the H-P-O axis resulting in the periodic release of oocytes; subsequent to menopause, the ovary functions as a relatively quiescent androgen-secreting organ in a hypergonadotropic environment. The molecular and cellular mechanisms involved in the increased magnitude of the rise in early follicular phase FSH, the development of menstrual cycle irregularity, the rise in LH late in the menopausal process, the regulation of E2, progesterone and inhibin levels during the menopausal process, and the apparent acceleration in the rate of follicular loss early in the menopausal process are largely unknown.

By what molecular mechanisms do the menopause-related changes in the aging H-P-O axis interact with non-reproductive tissues leading to the health problems and conditions associated with peri- and postmenopausal women? Clearly the loss of ovarian estrogen is a major factor involved in this process, as we learn that many non-reproductive tissues are responsive to protection by estrogen. Increased estrogen levels during the perimenopause coupled with declining progesterone levels may explain abnormal uterine bleeding and perhaps the development of uterine fibroids. Several non-reproductive somatic tissues associated with postmenopausal health problems, such as bone and cardiovascular tissue, make their own supply of estrogen via endogenous estrogen synthetase (aromatase) and/or activate estrogen within the tissue via endogenous 17-beta hydroxysteroid dehydrogenase activity.

Other H-P-O axis factors may also be involved. For example, the observations that a) gonadotropin levels are increased in estrogen-deficient postmenopausal women, b) glycosylated forms of serum LH and FSH are altered in the postmenopause, and c) gonadotropin receptors have been detected in non-reproductive tissue, increase the possibility that these altered postmenopausal levels and forms of gonadotropins may have physiologic or pathophysiologic roles outside of the reproductive system. Also, loss of gonadal inhibin in peri- and postmenopausal women may affect osteoblastogenesis and osteoclastogenesis, thereby contributing to bone loss during and subsequent to the menopause. The frequently greater complaint of menopausal symptoms in surgically menopausal women suggests either the severity is related to the abrupt loss of ovarian estrogen or the postmenopausal ovary may secrete protective factors to modulate symptoms. Still another largely unexplored possibility is age-related alteration in tissue sensitivity to estrogen and/or other bioregulatory factors secreted by the H-P-O axis.

A recent international conference (International Conference on Biology of Menopause, September 10-13, 1998, Newport Beach, CA), co-sponsored by Serono Symposia USA and the National Institute on Aging, was devoted to basic research issues related to the menopausal process and its interaction with the brain, cardiovascular, and skeletal systems. The proceedings of this conference, containing further information regarding studies that resulted in the findings described above, is available in the Serono Symposia USA Series (Bellino, FL (ed) Biology of Menopause, Springer-Verlag, New York, 2000).

Goals of the Program Announcement

This program announcement invites research applications focused on the underlying biologic mechanisms of molecular regulatory factors (a) acting within and external to the H-P-O axis that are responsible for female reproductive aging processes, and (b) secreted from the H-P-O axis of women that serve to maintain extra-ovarian tissue (e.g., cardiovascular, bone, urinary, brain) function and diminish their protective effects during the peri- or postmenopausal periods.

The goal is to increase our understanding of the molecular basis of the normal menopausal process occurring in women generally between the ages of 45 and 55. Premature ovarian failure, due either to iatrogenic or pathologic processes, is not within the scope of this program announcement. However, this restriction is not intended to exclude research with animal or other models in which ovarian follicular exhaustion is manipulated experimentally or genetically to explore relationships of reproductive aging with follicular number.

Although molecular and cellular mechanistic approaches to the issues described in this program announcement are strongly desired, the acquisition of more baseline data may be necessary in some areas to formulate a mechanistic hypothesis. Research questions of interest include, but are not limited to, the following:

o What regulates the process responsible for the enhanced rate of follicular loss in the last 12 to 15 years of menstrual cycling; what role do the hormonal interactions of the H-P-O axis play in this process;

o How do the declining numbers of ovarian follicles, and associated changes in the secretory products, in the aging ovary influence the process of the H-P-O axis intercommunication to result in acyclicity and eventual cessation of menstruation;

o How do paracrine and autocrine processes within the aging ovary influence its function, and how are these processes regulated by extra-ovarian tissues;

o What is the role of age-, central nervous system-, and ovarian-related changes in the pattern of pulsatile hypothalamic GnRH secretion on gonadotropin synthesis and release; how do these changes affect ovarian function;

o What changes occur during the peri- and postmenopause in posttranslational processing, including glycosylation, of the pituitary gonadotropins; do these changes affect function of various reproductive and non-reproductive tissues relative to the menopausal process and the development of associated health problems; by what mechanisms do these changes occur;

o Are there age- or menopause-related changes in tissue sensitivity to estrogens and other bioregulatory factors secreted by the H-P-O axis; by what molecular and cellular mechanisms do these changes occur;

o Does the reproductive history, as expressed by altered ovarian cellular components (due to, for example, different extents of regressed follicular or luteal tissue) affect the reproductive aging process or mechanisms underlying peri- or postmenopausal health problems;

o What is the role of endogenous estrogen made in non-reproductive tissues associated with peri- and postmenopausal health problems, such as bone and cardiovascular tissue, relative to serum estrogen supplied by the ovary; why are apparent estrogen-protective effects diminished in these tissues after menopause;

o If age-related changes in vascular supply to the ovary play an important role in change of ovarian function across the menopause, what are the mechanisms for these changes and how do they influence ovarian function;

o The NIDDK is interested in basic molecular mechanisms of how hormonal signals and other regulatory factors impact upon the function of the hypothalamic-pituitary-ovarian axis.

o The NICHD is particularly interested in the perimenopausal or age-associated factors that may influence fertility in the last 12-15 years of menstrual cycling.

Research Resources

The ability to conduct definitive studies into the molecular and cellular mechanisms of the menopausal transition and the associated change in non-reproductive tissue function is restricted in women by ethical concerns as well as by issues of practicality and experimental design. Consequently, it is necessary to utilize appropriate experimental models of the human menopausal process and development of pathophysiologic sequelae associated with the menopause.

Investigators are encouraged to develop and/or utilize appropriate animal models. A non-primate animal model of menopause may be acceptable for particular studies provided that the selection of the animal model is based on current and expanding knowledge available regarding (a) the human menopausal process and associated changes in tissue or organ function, and (b) characteristics and appropriateness of particular animal species to answer the research questions posed using relevant experimental approaches (Bellino FL, Nonprimate Animal Models of menopause: Workshop Report, Menopause 7: 14-24, 2000) . For example, it may be possible to experimentally manipulate in a physiologic fashion ovarian follicle number or rate of follicular decline in order to explore their relationship to reproductive aging and associated tissue decline. Although extensive research experience and background data on female reproductive aging has been accumulated in the rodent, some features of reproductive aging in the female rodent are substantially different from the human menopausal process. Since for other species less extensive background data on female reproductive aging are available, more preliminary data from the investigator will be required if use of these animal species is proposed.

A potential choice for a model of the human menopause based both on the phylogenetic relationship of species and the known physiologic similarities is the non-human primate. From the limited data available, the rhesus monkey and baboon may be suitable animal models of both the menopausal process and the subsequent decline in tissue function due to both menopause and aging. Investigators may choose to utilize non-human primates, particularly in collaboration with established primate research centers, including the Regional Primate Research Centers (RPRC) supported by the National Center for Research Resources (NCRR), NIH. However, there are drawbacks to the extensive and immediate use of these species, such as the high cost of husbandry (which is partially offset by maintenance of groups of aging animals at the RPRC by the NIA), relatively long life span, limited availability, and the limited published baseline data on female reproductive aging in non-human primates. For further information on the use and availability of middle-aged and older non-human primates, please contact the Head of the Office of Biological Resources and Resource Development at the NIA, Dr. Nancy Nadon, at 301 496-6402 (phone), 301 402-0010 (fax), or by email (nadonn@exmur.nia.nih.gov).

Other appropriate experimental models include (a) in vitro cell and tissue culture models using human tissues, or specimens derived from human tissues, (b) use of human post-mortem tissue where appropriate, and (c) implantation of relevant human tissues into pertinent animal species to approach questions regarding the behavior of that tissue under suitable experimental conditions. While clinical and epidemiological studies are not encouraged in response to this program announcement, the use of clinically derived data in characterizing the human tissues used for these studies would be appropriate.

INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

It is the policy of the NIH that women and members of minority groups and their sub-populations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43).

All investigators proposing research involving human subjects should read the UPDATED "NIH Guidelines for Inclusion of Women and Minorities as Subjects in Clinical Research," published in the NIH Guide for Grants and Contracts on August 2, 2000 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html);
a complete copy of the updated Guidelines are available at http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm:
The revisions relate to NIH defined Phase III clinical trials and require: a) all applications or proposals and/or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethnic groups, including subgroups if applicable; and b) all investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences.

URLS IN NIH GRANT APPLICATIONS OR APPENDICES

All applications and proposals for NIH funding must be self-contained within specified page limitations. Unless otherwise specified in an NIH solicitation, internet addresses (URLs) should not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites. Reviewers are cautioned that their anonymity may be compromised when they directly access an Internet site.

APPLICATION PROCEDURES

Applications are to be submitted on grant application form PHS 398 (rev. 4/98) and will be accepted at the standard application deadlines as indicated in the application kit. Application kits are available at most institutional offices of sponsored research and may be obtained from the Division of Extramural Outreach and Information Resources, National Institutes of Health, 6701 Rockledge Drive, MSC 7910, Bethesda, MD 20892-7910, Phone (301) 435-0714, Email: GRANTSINFO@NIH.GOV. Applications are also available on the internet at http://grants.nih.gov/grants/funding/phs398/phs398.html.

Applicants planning to submit an investigator-initiated new (type 1), competing continuation (type 2), competing supplement, or any amended/revised version of the preceding grant application types requesting $500,000 or more in direct costs for any year are advised that they must contact the Institute or Center (IC) program staff before submitting the application, i.e., as plans for the study are being developed. Furthermore, applicants must obtain agreement from the IC staff that the IC will accept the application for consideration for award. Finally, applicants must identify, in a cover letter sent with the application, the staff member and Institute or Center who agreed to accept assignment of the application.

This policy requires applicants to obtain agreement for acceptance of both any such application and any such subsequent amendment. Refer to the NIH Guide for Grants and Contracts, March 20, 1998 at: http://grants.nih.gov/grants/guide/notice-files/not98-030.html

Submit a signed, typewritten, original of the application, including the checklist and five signed photocopies in one package to:

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

The title and number of the program announcement must be typed on line 2 of the face page of the application form and the YES box must be marked.

SPECIFIC APPLICATION INSTRUCTIONS FOR MODULAR GRANTS

The modular grant concept establishes specific modules in which direct costs may be requested as well as a maximum level for requested budgets. Only limited budgetary information is required under this approach. The just-in-time concept allows applicants to submit certain information only when there is a possibility for an award. It is anticipated that these changes will reduce the administrative burden for the applicants, reviewers and Institute staff. The research grant application form PHS 398 (rev. 4/98) is to be used in applying for these grants, with the modifications noted below.

BUDGET INSTRUCTIONS

Modular Grant applications will request direct costs in $25,000 modules, up to a total direct cost request of $250,000 per year. (Applications that request more than $250,000 direct costs in any year must follow the traditional PHS398 application instructions.) The total direct costs must be requested in accordance with the program guidelines and the modifications made to the standard PHS 398 application instructions described below:

PHS 398

o FACE PAGE: Items 7a and 7b should be completed, indicating Direct Costs (in $25,000 increments up to a maximum of $250,000) and Total Costs [Modular Total Direct plus Facilities and Administrative (F&A) costs] for the initial budget period. Items 8a and 8b should be completed indicating the Direct and Total Costs for the entire proposed period of support.

o DETAILED BUDGET FOR THE INITIAL BUDGET PERIOD - Do not complete Form Page 4 of the PHS 398. It is not required and will not be accepted with the application.

o BUDGET FOR THE ENTIRE PROPOSED PERIOD OF SUPPORT - Do not complete the categorical budget table on Form Page 5 of the PHS 398. It is not required and will not be accepted with the application.

o NARRATIVE BUDGET JUSTIFICATION - Prepare a Modular Grant Budget Narrative page. (See http://grants.nih.gov/grants/funding/modular/modular.htm for sample pages.) At the top of the page, enter the total direct costs requested for each year. This is not a Form page.

o Under Personnel, list all project personnel, including their names, percent of effort, and roles on the project. No individual salary information should be provided. However, the applicant should

use the NIH appropriation language salary cap and the NIH policy for graduate student compensation in developing the budget request.

For Consortium/Contractual costs, provide an estimate of total costs (direct plus facilities and administrative) for each year, each rounded to the nearest $1,000. List the individuals/ organizations with whom consortium or contractual arrangements have been made, the percent effort of all personnel, and the role on the project. Indicate whether the collaborating institution is foreign or domestic. The total cost for a consortium/contractual arrangement is included in the overall requested modular direct cost amount. Include the Letter of Intent to establish a consortium.

Provide an additional narrative budget justification for any variation in the number of modules requested.

o BIOGRAPHICAL SKETCH - The Biographical Sketch provides information used by reviewers in the assessment of each individual's qualifications for a specific role in the proposed project, as well as to evaluate the overall qualifications of the research team. A biographical sketch is required for all key personnel, following the instructions below. No more than three pages may be used for each person. A sample biographical sketch may be viewed at: http://grants.nih.gov/grants/funding/modular/modular.htm.

- Complete the educational block at the top of the form page;
- List position(s) and any honors;
- Provide information, including overall goals and responsibilities, on research projects ongoing or completed during the last three years;
- List selected peer-reviewed publications, with full citations.

o CHECKLIST - This page should be completed and submitted with the application. If the F&A rate agreement has been established, indicate the type of agreement and the date. All appropriate exclusions must be applied in the calculation of the F&A costs for the initial budget period and all future budget years.

o The applicant should provide the name and phone number of the individual to contact concerning fiscal and administrative issues if additional information is necessary following the initial review.

REVIEW CONSIDERATIONS

Applications will be assigned on the basis of established Public Health Service referral guidelines. Applications will be reviewed for completeness by the Center for Scientific Review (CSR) and responsiveness by the Institutes (ICs). Applications that are complete will be evaluated for scientific and technical merit by an appropriate peer review group convened in accordance with NIH peer review procedures. As part of the initial merit review, all applications will receive a written critique and undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of applications under review, will be discussed, assigned a priority score, and receive a second level review by the appropriate national advisory council or board.

Review Criteria

The goals of NIH-supported research are to advance our understanding of biological systems, improve the control of disease, and enhance health. In the written comments reviewers will be asked to discuss the following aspects of the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

2. Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

3. Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

4. Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

5. Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

In addition to the above criteria, in accordance with NIH policy, all applications will also be reviewed with respect to the following:

o The adequacy of plans to include minorities and their subgroups, as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated.

o The reasonableness of the proposed budget and duration in relation to the proposed research.

o The adequacy of the proposed protection for humans, animals or the environment, to the extent they may be adversely affected by the project proposed in the application.

AWARD CRITERIA

Applications will compete for available funds with all other recommended applications. The following will be considered in making funding decisions:

o Quality of the proposed project as determined by peer review
o Availability of funds
o Program priority.

INQUIRIES

Inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Frank Bellino, Ph.D.
Biology of Aging Program
National Institute on Aging
7201 Wisconsin Avenue, Suite 2C231 MSC 9205
Bethesda, MD 20892-9205
Telephone: (301) 496-6402
FAX: (301) 402-0010
Email: FB12A@nih.gov

William J. Sharrock, Ph.D.
Musculoskeletal Diseases Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Natcher Building, Room 5AS-37A, MSC 6500
Bethesda, MD 20892-6500
Telephone: (301) 594-5055
FAX: (301) 480-4543
Email: ws19h@nih.gov

Estella Parrott, M.D., M.P.H.
Center for Population Research
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8B01, MSC 7510
Bethesda, MD 20892-7510
Telephone: (301) 496-6515
FAX: (301) 496-0962
E-mail: ep61h@nih.gov

Sheryl M. Sato, Ph.D.
Director, Cellular Basis of Metabolic Diseases Program
National Institute of Diabetes and Digestive and Kidney Diseases
2 Democracy Plaza, Room 6105
6707 Democracy Boulevard, MSC 5460
Bethesda, MD 20892
(301) 594-8811
FAX (301) 480-3503
satos@extra.niddk.nih.gov

Direct inquiries regarding fiscal matters to:

Linda Whipp
Grants and Contracts Management Office
National Institute on Aging
7201 Wisconsin Avenue, Suite 2N212, MSC 9205
Bethesda, MD 20892-9205
Telephone: (301) 496-1472
FAX: (301) 402-3672
Email: whippl@exmur.nia.nih.gov

Melinda Nelson
Grants Management Officer
Grants Management Branch
National Institute of Arthritis and Musculoskeletal and Skin Diseases
45 Center Drive, Room 5AS49
Bethesda, Maryland 20892
Telephone: (301) 435-5278
Fax: (301) 480-5450
E-mail: mn23z@nih.gov

Kathy Hancock
Lead Grants Management Specialist
National Institute of Child Health and Human Development
6100 Executive Boulevard, Room 8A17M, MSC 7510
Bethesda, MD 20892-7510
Phone: 301-496-5482
Fax: 301-402-0915
E-mail: hancockk@mail.nih.gov

Mr. Kieran Kelley
Grant Management Specialist
National Institute of Diabetes and Digestive and Kidney Diseases
2 Democracy Plaza
6707 Democracy Boulevard, MSC 5456
Bethesda, MD 20892
(301) 594-0417

FAX (301) 480-3504
kelleyk@extra.niddk.nih.gov

AUTHORITY AND REGULATIONS

This program is described in the Catalog of Federal Domestic Assistance Nos. 93.866 (NIA), 93.864 (NICHD), 93.846 (NIAMS), 93.847 (NIDDK). Awards are made under authorization of sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and administered under NIH grants policies and Federal Regulations 42 CFR 52 and 45 CFR Parts 74 and 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

The PHS strongly encourages all grant and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

Return to Volume Index
Return to NIH Guide Main Index